

## REMARKS

Claims 1-21 are active. Claims 1 – 22 are subject to restriction. Applicant elected the claims of Group II, claims 12 – 22, drawn to a method of correcting an imbalance between two muscles. Claims 1-11 are withdrawn from consideration. Claims 12-21 are rejected under 35 USC 103 as being unpatentable over Hurtado in view of Axelgaard.

Applicant traverses the rejection of claims 12-21. Claim 12 is directed to a method of correcting a bunion condition in a foot.

The Office action agrees that the references are foreign to correcting a bunion condition and then states it is obvious to apply electrical signals to the foot. No reason is given and this is not what is claimed. The claim is not applying signals to the foot, which has numerous muscles, but to specific muscles. No reason is given as to why it is obvious to apply the signals as claimed to specific muscles. The Office Action is silent to this. This is not a proper basis for the rejection.

Claim 1 calls for the step of attaching one electrode to the foot for applying an electrical signal to the abductor hallucis muscle to counter balance the strength of the adductor hallucis muscle. Hurtado and Axelgaard, individually or in combination are foreign to this claimed method. Neither reference points one of ordinary skill as to the cause of a bunion condition in the foot or how to correct such a condition as admitted by the Office Action.

A bunion condition as disclosed by applicant is caused by one muscle, the adductor hallucis being stronger than the abductor hallucis muscle in the foot. Claim 12 calls for:

A method of correction a bunion condition in a foot comprising the step of applying an electrical signal to the abductor hallucis muscle to strengthen the abductor hallucis muscle to correct for an imbalance between the two muscles.

Hurtado discloses electro-muscle stimulation (EMS) system that applies an electrical signal to abdominal muscle to cause the muscle to contract. In particular, he discloses a belt or band which is snugly wrapped about a patient's body, and in particular an abdominal belt. In another embodiment, he discloses an extremity cuff which stimulates the muscles in the legs and arms. Two cuffs are preferred. He discloses a problem with quadriceps associated with a deranged patella and sees a need to correct this condition

by development of the quadriceps. In particular a belt is disclosed for wrapping about a patient's body. Col. 3, lines 3 et seq. Also a cuff is disclosed for stimulating muscles in the legs or arms. Col. 3, lines 54 et seq. Two cuffs are disclosed, one with positive electrodes and the other with negative electrodes. Col. 3, lines 58 et seq. An abdominal belt may be provided. Col. 4, lines 48 et seq. The reference specifically refers to the quadriceps, col. 4, line 35, patella, col. 4, line 40, and abdominus rectus, Col. 4, line 52. With respect to the latter, the oblique muscles are stimulated equally. Col. 5, line 67. This patent is foreign to the claimed method directed to the abductor hallucis muscle.

There is no discussion in this reference as to the cause of a bunion condition nor is there any discussion relating to how to correct for a bunion condition. The disclosed apparatus is not directed to correcting such a condition. There is no relevant teaching to one of ordinary skill of either the cause of a bunion condition, and, even if such cause were known, there is no teaching or disclosure of the concept of correcting such a condition. The reference does not disclose that such a condition is correctable, and even more remote, plainly its disclosed electrical stimulation apparatus will not correct such a condition, since it is not capable of applying signals to the abductor hallucis muscle much less signals of the correct value. In other words, simply because it is known to stimulate abdominal and limb muscles can not be extrapolated to manifest that the abductor hallucis muscle will be sufficiently strengthened by this process to over come and correct the bunion condition. This reference does not go so far and is at best an invitation to try, which is proscribed. A reference that only invites experimentation is not a valid reference.

MPEP 2144.05. This reference does not suggest a result effective variable to correct a bunion condition since there is no teaching therein of such a condition and whether or not such a condition is so correctable generally with electrical stimulation. With no such suggestion, this reference is a mere invitation to experiment, which is not a test of obviousness. *In re Antonie*. MPEP 2144.05.

The Office Action admits that this reference does not disclose correcting a bunion condition by applying an electrical signal to the abductor hallucis muscle. But then goes on to state it would be obvious to one of ordinary skill to apply the claimed method to a foot. There is no support in this reference for this conclusion. This reference discloses that as a first positive voltage increases a second positive voltage decrease. Col. 11,

lines 30-32 and 63-65. This system operates as a stereo system acting as a balance control. Such a system has no support in this reference as being capable of correcting a bunion condition and no evidence to do so is supplied by the Office Action. Applicant's disclosure is foreign to this treatment. The claimed method is not directed to applying the signal to a foot, but to a particular muscle to correct a particular condition.

The reference does not point one of ordinary skill to the particular claimed muscle, and more importantly, does not suggest that doing so will correct the condition, and certainly there is no evidence of record that what works on the abdominal muscles is operative on the abductor hallucis muscle. It is one thing to stimulate a muscle and another to strengthen a muscle sufficiently to counter balance another specified muscle to correct the bunion condition. This reference does not go so far. No convincing line of reasoning is given for the bare conclusion.

There are numerous muscles in the body. No convincing line of reasoning is given as to why the claimed abductor hallucis muscle would be responsive to an electrical signal disclosed by this reference to correct the bunion condition. The signals of the values as disclosed by applicant have to be applied in a certain manner and in a certain region. The reference does not point out what this certain manner or region is or whether this manner would be operative or whether this region is even available for such stimulation, and if it is, where on the muscle to apply the signal(s) and the values of such signals and so on. Applicant does that, not the reference.

Discovering the source of the problem is part of the invention of a whole that needs to be considered. The problem is bunions. Neither cited reference is concerned with this problem. MPEP 2141.02, page 2100-120, 121. The source of the problem is the recognition that the abductor hallucis muscle is weaker than the adductor hallucis muscle and is the cause of the condition and that by strengthening the abductor hallucis muscle would alleviate the problem. The knowledge that generally electrical signals can alleviate certain muscle problems, the abdominal, leg and arm muscles, is of no help in this context. The references do not teach or suggest what is claimed.

The prior art must be considered in its entirety including that which teaches away. MPEP 2143.03 page 2100-122. To establish *Prima facie* obviousness, there must be some suggestion or motivation in the prior art to do what is claimed. MPEP 2143. See *In*

*re Fine* cited by the MPEP. The fact that the references disclose different elements of the claimed combination is insufficient if there is no motivation to combine them. The suggestion to combine must come from the references.

Axelgaard is cited for disclosing certain signal values because they more closely relate to applicant's signal values. Selecting this reference is based on improper picking and choosing only to select only so much from a reference that will meet a given need using applicant's disclosure as a guide. This reference is chosen based on applicant's disclosure and not based on any suggestion therein that such signals would be effective for the abductor hallucis muscle. This reference does not go so far and it is improper to so chose this reference without motivation from the references.

Hurtado also discloses signal values which may be AC, DC, pulse signals and so on such as at 3 and 1.5 volts. The user adjusts the voltage. Col. 9 lines 59 et seq. These signals are different than that of Axelgaard. The Office Action gives no convincing reasoning as to why one of ordinary skill would want to use Axelgaard's disclosed values as compared to Huratdo's in a bunion situation since neither reference is relevant to the correction of a bunion condition. Again, the Office Action uses applicant's teachings as a proscribed hindsight guide to select the proper signals. Neither reference teaches what signals are useful for correcting the abductor hallucis muscle condition related to bunions as neither reference is concerned with the bunion condition.

In addition, Axelgaard applies the signals to the spinal muscles to correct for spinal deformities such as scoliosis. There is no correlation in this reference of the correction of the disclosed scoliosis condition to the correction of a bunion condition involving the abductor hallucis muscle. This reference is silent as to the abductor hallucis muscle. The Office Action is required to cite a reference. If the Examiner is basing his conclusions on personal knowledge, then he is required to supply an affidavit of personal knowledge 37 CFR 104(d). Simply because electrical signals are known to affect certain muscle conditions due to injury, surgery or otherwise, does not make it obvious to correct all muscle conditions, much less the abductor hallucis muscle condition at specific foot locations employing specific signals as claimed in certain of the claims without a teaching or disclosure of the nature of the problem.

Applicant's information disclosure cites a number of references purportedly dealing

with bunion conditions. These merely provide mechanical mechanisms or devices to treat the symptoms and not the cause. Neither of the cited references by the Office Action discuss or disclose the cause of the bunion condition. Further, assuming *arguendo* the cause of the condition is known, there is no suggestion that Hurtado or Axelgaard could resolve this particular problem or how. They are merely an invitation to experiment, which is proscribed. Neither reference provides motivation or suggests a result effective variable to correct a bunion condition. With no such suggestion, they are mere invitations to experiment, which is not a test of obviousness. *In re Antonie*.

MPEP2144.05 II B. The case states that a parameter optimized must be a result effective variable. The values of the signals used in the prior art are not suggested as being effective for bunion treatment. Applicant has discovered the particular frequency, amplitude and duration of the pulses, Figs. 10a and 10b, and claim 14, for example, which are result effective for bunion treatment. The fact that Axelgaard discloses even the same signals does not infer that such signals are also applicable to the abductor hallucis muscle. See Hurtado for example using different signals and MPEP 2143. The references do not suggest such signals for use in correcting the abductor hallucis muscle condition, much less a bunion condition and, therefore, are foreign to treating bunions. A reference that only invites experimentation is not a valid reference. MPEP 2144.05.

It should be understood that all muscles in the body are different. There is no support in the cited references that one set of muscles that may respond to one kind of electrical stimulation imparts a global conclusion that all muscles will respond similarly to the same signals or in fact, to any signals of any values and more significantly that such treatment will correct a bunion condition. This is not true and the references do not support such a conclusion.

More importantly, the response of various muscle groups to stimulation is unpredictable. It is not know which muscles of the body will respond to stimulation or in fact the kind of stimulation necessary to achieve a desired result. That is, electrical signals useful for one set of muscles may not necessarily work in the same way on other different sets of muscles. The cited references show this. There is no support in the cited references that applying the signals to the abdominal muscles, leg, spine or arm muscles or other disclosed muscles suggest that the muscles causing the bunion

condition will be responsive to such stimulation to alleviate the condition or, if responsive, how to do so with what signal values and where. Applying signals to the various muscles specified in the references does not provide a clue as to which muscles, where and what value signals are needed, to correct the bunion condition. The fact that certain signals useful for some muscles may overlap uses with other muscles does not make it obvious to one of ordinary skill of what is operative. This is unpredictable.

Axelgaard is only concerned with the spine and Hurtado is only concerned with the abdominal muscles. There is no support in the Axelgaard or Hurtado that their apparatus would or could work to correct the bunion condition. The Office Action extrapolates unrelated problems and solutions to the claim 12 method. But those solutions to the unrelated problems do not in any way suggest how to solve a bunion condition or even if such solutions can even be employed to correct a bunion condition. Applicant in fact has shown that those disclosed solutions are not the same as what applicant discloses and thus will not in practice solve the bunion condition problem. That is applicant's contribution and not that of the references. Applicant teaches what muscles to stimulate, and what signals to use for such stimulation. The references do not do this. For the reasons given, Claim 12 is believed allowable.

Claims 13-21 are directed to specific solutions directed to bunion correction. The cited references are even more remote to these claims and at best are only an invitation to proscribed experiment. What will work on one set of muscles is no indication that other muscles will respond similarly. For example, the particular frequencies and pulse widths of claim 14 are not suggested by these cited references of record. These references do not go so far.

Claims 15 and 16 are also not specifically disclosed in the cited references. These dependent claims are believed further allowable for these additional reasons.

Since claims 12-21 have been shown to be in proper form for allowance, such action is respectfully requested.

Enclosed is a request for a two month extension of time to respond to the Office Action dated May 23, 2003 and a check in the amount of \$585 as the fee for this paper.

If any additional fee is due for this paper, the Commissioner is authorized to charge deposit account 03-0678 with respect to any underpayments or to credit that deposit account for any overpayments.

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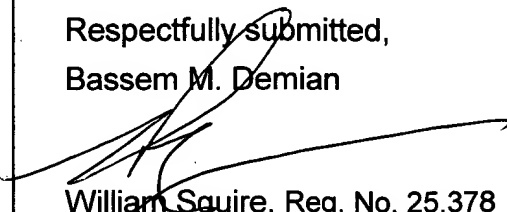
  
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**October 23, 2003**

**Date**

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